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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,364	11/10/2003	Steven Just	9354-2IP	4621

7590 11/14/2006

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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/705,364	JUST ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41 and 54-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,22,23,26-41 and 54-64* is/are rejected.

7)☒ Claim(s) *21,24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/20/04,7/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I in the reply filed on 10/30/06 is acknowledged. Claims corresponding to Invention II were cancelled by the applicant.

Regarding the election requirement between species A and B, the applicants' clearly admitted on the record that the inventions are obvious variants. The applicants' admission that the species re "sufficient similar in design and use as to overlap in scope" is taken to be an admission of obviousness. In light of this admission, the election requirement is withdrawn.

The applicants' arguments regarding the election requirement between species C, D, and E have been considered and are found persuasive. The election requirement between species C, D, and E has been withdrawn.

Claim Objections

Claims 10 and 57 are objected to because of the following informalities:

On line 4 of claim 10, "the second" should be replaced with "a second".

On line 1 of claim 57, "the opposing sleeve short edge portions" should be replaced with "opposing sleeve short edge portion".

On line 2 of claim 57, "the other sleeve short edge portion" should be replaced with "another short edge portion".

On line 3 of claim 57, "as closed' should be replaced with "a closed".

On line 3 of claim 57, "an axially aperture extending shape" should be replaced with "an aperture extending axially in shape" or similar language such that the language makes sense grammatically and otherwise. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 7 recites "the sleeve . . . resides securely against a desired portion of the limb of the patient". The human body and parts thereof are non-statutory subject matter and cannot be positively claimed. To overcome this rejection, "resides "on line 4 of claim 7 should be replaced with "is configured to reside".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 13, 15, 27-33 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,033,337 to Raczkowski. Raczkowski teaches an inflatable blood pressure cuff assembly comprising an inflatable elongated cuff member

14. The cuff member has opposing long edges (edges with hem 34) and opposing short edge portions (edges with guideway 29), with an inflatable fluid chamber 18 therein. A resilient sleeve 20 is attached to a respective one of the opposing short edge portions of the cuff member, the sleeve comprising at least one rib support member 26 (see entire document, especially figs. 1, 2, and 4; col. 2, lines 12-44 of Raczkowski).

Regarding claim 2, the at least one support member 26 has an elongated flexible body configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs 1 & 3; col. 2, lines 37-42 of Raczkowski), wherein the rigidity of a member meant to stiffen the body of the cuff would necessarily be configured to inhibit rolling of the upper portion of the sleeve and wherein "relatively rigid" implies that the member has some flexibility.

Regarding claim 3, the sleeve comprises at least one rib channel, formed by the hem at an edge of sleeve 20, sized and configured to hold the support member therein (see entire document, especially, fig. 1; col. 2, lines 37-42 of Raczkowski).

Regarding claim 4, the at least one rib support member is a plurality of laterally spaced apart rib support members 26, 28 configured to inhibit an upper edge portion from rolling down when in position on a user (see entire document, especially figs. 1 & 4; col. 2, lines 37-42 of Raczkowski).

Regarding claim 13, the sleeve may have a frustoconical shape, or a shape resembling the frustum of a cone (see entire document, especially fig. 3 of Raczkowski), wherein, when the cuff and sleeve are placed on a patient's arm and secured, the cuff and sleeve may take a frustoconical shape since the diameter of the arm become

progressive smaller in a direction, for example, in a direction from the bicep towards the elbow.

Regarding claim 15, the cuff member comprises a pouch 12 and an inflatable bladder 18 configured to reside therein (see entire document, especially figs. 1 & 3; col. 2, lines 24-26 of Raczkowski).

Regarding claims 27 and 28, the sleeve is attached to the cuff member in a releasably detachable manner (see entire document, especially figs. 1 & 4 of Raczkowski), wherein the sleeve is clearly capable of being released (release meaning to set free from something that fastens) and/or detached (detach meaning to separate or disconnect) from the cuff member. With further regard to claim 28, the applicant should note that the language "single-use disposable" is merely "intended use" language that cannot be relied upon to define over the prior art, since Raczkowski teaches all of the claimed structural elements and their recited relationships. The assembly of Raczkowski is clearly capable of being used a single time and/or of being thrown away after use.

Regarding claim 29, the sleeve is fixedly attached to the cuff member (see entire document, especially fig. 2 of Raczkowski).

Regarding claim 30, the sleeve has opposing first and second short end portions, the first end portion is configured to releasably attach to the cuff member and/or the second short end portion of the sleeve (see entire document, especially figs. 1 & 3 of Raczkowski). As to the language "releasably attach", the figures of Raczkowski show the first end portion of the sleeve being attached to the cuff member and the end portion

is certainly capable of being released or set free from the cuff member, such that the end portion is configured to releasably attach to the cuff member. Alternatively or in addition, the first end portion is configured to releasably attach to the second short end portion of the sleeve via hook and loop material 30.

Regarding claim 31, the cuff member and sleeve are configured to accommodate both the left and right arms of the patients (see entire document, especially fig. 3 of Raczkowski).

Regarding claims 32 and 33, the assembly is configured for ambulatory or stress test blood pressure measurements (see entire document), wherein the language "ambulatory" and "stress test" are merely intended use language and the device is clearly capable of use by patients who are not bedridden or who are "ambulatory" or during a stress test.

Claims 34-36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,669,390 to McCormick et al. McCormick teaches an inflatable blood pressure cuff assembly comprising an inflatable elongate cuff member 12 having opposing long edges and opposing short edge portions with a fluid chamber therein, in operation, the short edge portions being configured to wrap about a body portion of a user and connect to each other (see entire document, especially figs. 2B, 2C, 3; col. 1, lines 53-59; col. 4, lines 20-32 of McCormick). A resilient sleeve 1 is configured to reside under the wrapped cuff member, wherein the sleeve comprises at least one rib

support member 4 (see entire document, especially figs. 1, 2B, 2C; col. 3, lines 36-47 of McCormick).

Regarding claim 35, the rib support 4 has an elongate flexible body configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 1 & 2A; col. 3, lines 40-48; col. 4, lines 16-20 of McCormick).

Regarding claim 36, the sleeve is configured with at least one rib channel sized and configured to hold the at least one rib support member therein (see entire document, especially fig. 1; col. 3, lines 43-47 of McCormick).

Regarding claim 38, the sleeve remains unattached to the cuff member during operation see entire document, especially figs. 2B & 2C of McCormick).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 7, 13, 14, 27-32, 34-37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,033,337 to Raczkowski in view of US Patent No. 5,797,851 to Byrd. Raczkowski teaches an inflatable blood pressure cuff assembly comprising an inflatable elongate cuff member 18 having opposing long edges and opposing short edge portions with an inflatable chamber therein (see entire

document, especially figs. 1-3; col. 2, lines 24-28 of Raczkowski). A resilient sleeve 12, 14 surrounds the cuff member 18 and comprises at least one rib support member 24, 26, 28 (see entire document, especially figs. 1, 2, and 4; col. 2, lines 29-44 of Raczkowski). Although the cuff member is shown as being disposed within the sleeve, Raczkowski is silent as to the whether or not the sleeve and cuff member are attached.

However, Byrd teaches an inflatable blood pressure cuff assembly comprising a inflatable elongate cuff member 22 attached to a resilient sleeve 14 at one of the opposing short edge portions of the cuff member (see entire document, especially fig. 2; col. 4, lines 1-13 of Byrd). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the attachment of the cuff member and sleeve, as described by Byrd in the assembly of Raczkowski, since Raczkowski teaches an assembly wherein the cuff member resides within the sleeve and Byrd describes attachment of the cuff member and sleeve suitable for an inflatable blood pressure cuff assembly. Additionally, the use of the attachment of Byrd would result in preventing movement of cuff member, so as to facilitate accurate use of the cuff assembly.

Regarding claims 2 and 35, the rib member has an elongate flexible body configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 1 & 2 and col. 2, lines 33-42 of Raczkowski).

Regarding claims 3 and 36, the sleeve comprises at least one rib channel sized and configured to hold the support member therein (see entire document, especially figs. 1 & 4 of Raczkowski).

Regarding claims 4 and 37, the at least one rib support member is a plurality of laterally spaced apart rib support members 24, 26, 28 configured to inhibit an upper edge portion from rolling down (see entire document, especially figs. 1 & 2 and col. 2, lines 33-42 of Raczkowski).

Regarding claims 6 and 7, the sleeve has a closed perimeter configuration defining an aperture extending in the axial direction, wherein the sleeve is sized and configured to stretch to receive a limb therein during use (see entire document, especially figs. 1 & 3 of Raczkowski). With further regard to claim 7, the sleeve aperture has first configuration with a first width during periods of non-use, wherein during non-use the elastic members 16 are relaxed, and a second configuration with an expanded second width when in position on a patient, wherein, depending on the width of the arm, the elastic members 16 may require stretching to accommodate the limb. In the second configuration, the sleeve is substantially conformable to and, may reside securely against a limb portion with sufficient compressive force so as to maintain its position to thereby inhibit slippage, depending on the width of the user's arm with respect to the sleeve.

Regarding claim 13, since the sleeve is configured to conform to the shape of the user's arm, especially when the strip body 20 is wrapped, the sleeve may acquire a frustoconical shape during use, especially in a case wherein the portion of the user's arm, on which the sleeve is placed, has a diameter that increases in a direction, such as from above the elbow towards the bicep.

Regarding claim 14, the cuff member is bladderless (see entire document, especially fig. 1 and col.2, lines 25-39 of Raczkowski).

Regarding claims 27 and 39, the sleeve is attached to the cuff member in a releasably detachable manner (see entire document, especially col. 4, lines 1-13 of Byrd).

As to the language "single-use" and "disposable" in claim 28, the applicants should note that this is merely "intended use" language, and the apparatus of Raczkowski, as modified, is fully capable of being used once and thrown away.

Regarding claims 29 and 40, the sleeve is fixedly attached to the cuff member (see entire document, especially col.4, lines 1-13 of Byrd).

Regarding claims 30 and 41, the sleeve has opposing first and second short end portions and the first end portion is configured to releasably attach to at least the cuff member (see entire document, especially fig. 2 of Byrd).

Regarding claim 31, the cuff member and sleeve are configured to accommodate both the left and the right arms of the patient.

As to the language "ambulatory" in claim 32 and "stress test" in claim 33, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Raczkowski, in view of Byrd, teaches all of the claimed structural elements and the recited relationships. The assembly of Raczkowski, as modified, is fully capable of being used on an ambulatory patient or during a stress test.

Regarding claims 34-37 and 39-41, the short edges of the cuff member are configured to connect to each other via elastic member 16 and the sleeve 12, 14, 20 is configured to reside both under and over the wrapped cuff member when applied to the patient's limb (see entire document, especially figs. 1 & 3 of Raczkowski).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raczkowski, as applied to claims 1-4, 13, 15, 27-33, and further in view of US Patent No. 5,797,851 to Byrd. Raczkowski teaches that the sleeve material may be a flexible sheet material, but is silent as to the particular material. However, Byrd teaches an inflatable blood pressure cuff assembly wherein a flexible sheet material of spun bond polypropylene is used for the inflatable elongate cuff member and sleeve attached thereto (see entire document, especially col. 3, lines 51-55 of Byrd). Spun bond polypropylene is air permeable and comprises a fabric that includes stretch fibers. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the spun bond polypropylene of Byrd as the flexible sheet material for the sleeve of Raczkowski, since Raczkowski teaches using a flexible sheet material, and Byrd teaches spun bond polypropylene as an appropriate such material.

Claims 5, 8, 9, 16, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raczkowski, as applied to claims 1-4, 13, 15, 27-33 above, and further in view of US Patent No. 5,344,406 to Spooner. Raczkowski teaches that the sleeve may be a flexible sheet material, but is silent as to the particular material.

However, Spooner teaches a sleeve of a material made with nylon fibers and spandex fibers, the material being air permeable and the sleeve being suitable for medical applications (see entire document, especially col. 4, lines 3-14 of Spooner). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the material of Spooner as that of Raczkowski, since Raczkowski teaches using a flexible sheet material and Spooner describes an appropriate such material.

Regarding claim 16, the fabric comprises nylon as a major constituent and spandex as a minor constituent (see entire document, especially col. 4, lines 5-13; col. 6, lines 1-38 of Spooner).

Regarding claim 26, the material is inherently anisotropic since the material is made up of one type of fiber having its own qualities of stretch in a lengthwise direction and a different type of fiber having a different quality of stretch in a widthwise direction (see entire document, especially col.4, lines 3-27 of Spooner).

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raczkowski in view of Byrd, as applied to claim 5 above. Raczkowski, as modified, fails to address the amount of stretch afforded by the material. However, the applicants have not disclose that the amount of at least 15% elastic lateral stretch at the lower edge portion to provide the second configuration width solves any stated problem or is for any particular purpose. Moreover, it appears that the cuff assembly would perform equally well having any amount of stretch. Accordingly, the use of at least about 15% of

elastic stretch is deemed to be a design consideration that fails to patentably distinguish over the prior art.

Regarding claims 11 and 12, it appears that the sleeve is configured to accommodate patients having limbs that vary in width by up to at least about 150%, since the hook and loop material 30, 32 allows the sleeve to be wrapped around limbs of different sizes and an elastic material is used as the sleeve material.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raczkowski, as applied to claims 1-4, 13, 15, 27-33, and further in view of US Patent No. 6,149,600 to Poorman-Ketchum. Raczkowski teaches a cuff having a pouch and inflatable bladder, rather than a "bladderless" cuff. However, Poorman-Ketchum teaches a blood pressure cuff assembly wherein the cuff may comprise either a pouch having a bladder disposed therein or a "bladderless" cuff (col. 3, lines 3-8 of Poorman-Ketchum). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a bladderless cuff in place of the cuff of Raczkowski, since Poorman-Ketchum teaches the two types of cuffs to be functionally equivalent and further in light of the applicants' own admission that the two types of cuff are obvious variants.

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raczkowski in view of Byrd, as applied to claims 1-4, 6, 7, 13, 14, 27-32, 34-37 and 39-41 above, and further in view of US Patent No. 5,492,129 to Greenberger. Raczkowski,

as modified, teaches the sleeve comprising a stethoscope head 36 (see entire document, especially fig. 2 & col. 3, lines 21-30 of Raczkowski), but fails to describe the details of the construction of the stethoscope head. However, Greenberger teaches a stethoscope head comprising a chamber formed by housing 20a and diaphragm 23 and having a sensor 24a therein (see entire document, especially fig. 1B and col. 6, lines 39-45 of Greenberger). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the stethoscope and stethoscope head of Greenberger as that of Raczkowski, as modified, since Raczkowski teaches using a stethoscope and Greenberger describes and appropriate such stethoscope.

Regarding claim 19, the sleeve comprises upper and lower edge portions, wherein the sensor chamber is located proximate the lower edge portion (see entire document, especially fig. 1 of Raczkowski).

Regarding claim 20, the sleeve sensor chamber has lower edge portion (diaphragm 23 or housing 20a) that is shown in figure 1B of Greenberger as being seamless.

Regarding claims 22 and 23, the sleeve further comprises a cable channel 36b in communication with the sensor chamber (see entirety of Raczkowski, especially figs. 2 & 3 and col. 3, lines 21-30; also see entirety of Greenberger, especially fig. 1B), wherein threaded shaft is capable of being used for a cable, for example the cable or tubing connecting the stethoscope head to the remainder of the stethoscope. With further regard to claim 23, the sleeve cable channel is curvilinear, in that the shaft is formed of curved lines (see entire document, especially fig. 2 of Raczkowski).

Claim 54-60, 63, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,626,142 to Marks in view of US Patent No. 4,033,337 to Raczkowski. Marks teaches an automated blood pressure monitoring system comprising a plurality of inflatable blood pressure cuff assemblies, each sized and configured to accommodate a different patient size range (see entire document, especially fig. 1; col. 1, lines 20-64; col. 4, lines 43-49 of Marks). An inflation unit is in fluid communication with a selected blood pressure cuff and configured to generate a pressure sufficient to restrict blood flow in a selected artery of a patient, and means for releasing inflation pressure and detecting a signal corresponding to blood pressure measurements are also included (see entire document, especially col. 4, lines 37-45 of Marks). Marks is silent as to the details of the cuff assemblies.

However, Raczkowski teaches a blood pressure cuff assembly comprising an inflatable elongated cuff member 14. The cuff member has opposing long edges (edges with hem 34) and opposing short edge portions (edges with guideway 29), with an inflatable fluid chamber 18 therein. A resilient sleeve 20 is attached to a respective one of the opposing short edge portions of the cuff member, the sleeve comprising at least one rib support member 26 (see entire document, especially figs. 1, 2, and 4; col. 2, lines 12-44 of Raczkowski). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to use the cuff assembly of Raczkowski as that of Marks, since Marks teaches using a blood pressure cuff assembly and Raczkowski describes an appropriate such assembly.

Regarding claim 55, the sleeves are fixedly attached to the corresponding cuff members (see entire document, especially fig. 2 of Raczkowski).

Regarding claim 56, the sleeve is releasably attached to the cuff member in that the end of the sleeve attached to the cuff member is capable of being released and the sleeve may also be releasably attached to the cuff member using the hook and loop material 30, 32 as shown in figure 3 (see entire document, especially figs. 1 & 3 of Raczkowski). With further regard to claim 57, one of the opposing sleeve short edge portions is configured to be releasably attached to the cuff member to define a closed sleeve having an aperture extending axially in shape (see entire document, especially fig. 3 of Raczkowski).

Regarding claim 58, the at least one support member 26 has an elongated flexible body configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs 1 & 3; col. 2, lines 37-42 of Raczkowski), wherein the rigidity of a member meant to stiffen the body of the cuff would necessarily be configured to inhibit rolling of the upper portion of the sleeve and wherein "relatively rigid" implies that the member has some flexibility.

Regarding claim 59, the sleeve comprises at least one rib channel, formed by the hem at an edge of sleeve 20, sized and configured to hold the support member therein (see entire document, especially, fig. 1; col. 2, lines 37-42 of Raczkowski).

Regarding claim 60, the at least one rib support member is a plurality of laterally spaced apart rib support members 26, 28 configured to inhibit an upper edge portion

from rolling down when in position on a user (see entire document, especially figs. 1 & 4; col. 2, lines 37-42 of Raczkowski).

Regarding claims 63 and 64, the assembly is configured for ambulatory or stress test blood pressure measurements (see entire document of Marks and Raczkowski), wherein the language "ambulatory" and "stress test" are merely intended use language and the device is clearly capable of use by patients who are not bedridden or who are "ambulatory" or during a stress test

Claims 54-59, and 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Us Patent No. 5,626,142 to Marks in view of US Patent No. 5,669,390 to McCormick et al., and further in view of US Patent No. 4,967,758 to Masciarotte. Marks teaches an automated blood pressure monitoring system comprising a plurality of inflatable blood pressure cuff assemblies, each sized and configured to accommodate a different patient size range (see entire document, especially fig. 1; col. 1, lines 20-64; col. 4, lines 43-49 of Marks). An inflation unit is in fluid communication with a selected blood pressure cuff and configured to generate a pressure sufficient to restrict blood flow in a selected artery of a patient, and means for releasing inflation pressure and detecting a signal corresponding to blood pressure measurements are also included (see entire document, especially col. 4, lines 37-45 of Marks). However, Marks is silent as to the details of the cuff assemblies.

However, McCormick teaches a cuff assembly comprising an elongate cuff member 12 having opposing long edges and opposing short edge portions with an

inflatable fluid chamber therein and a resilient sleeve 1 having a predetermined patient size range, wherein the sleeve comprises at least one rib support member 4 (see entire document, especially figs. 2B, 2C, & 3; col. 3, lines 40-47; col. 4, lines 20-47; col. 5, lines 50-57 of McCormick). Therefore, it would have been obvious to use the cuff assembly of McCormick as that of Marks, since Marks teaches using a cuff assembly and McCormick describes an appropriate such assembly. Marks, as modified lacks the sleeve being attachable and/or attached to a short edge portion of the cuff member.

However, Masciarotte teaches an inflatable blood pressure cuff assembly comprising a sleeve and a cuff member, wherein the sleeve may be attached to the short edge portion of a cuff member (see entire document, especially fig. 2; col. 3, lines 35-44 of Masciarotte), wherein adhesive 4 disposed on the entirety of the surface 3 allows such attachment to at least the short edge portion of the cuff member. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to attach the sleeve to the cuff member as shown in Masciarotte in the system of Marks, as modified by McCormick, in order to further ensure that the sleeve and cuff member are held in place with respect to each other. Alternatively, since Masciarotte shows both an embodiment where the sleeve and member are attached and an embodiment where they are not, it would have been obvious to one of ordinary skill in the art at the time of invention to attach the sleeve and cuff member of Marks, as modified by McCormick in the manner described by Masciarotte, since Masciarotte shows attachment and non-attachment to be functionally equivalent means of using the sleeve and member co-operatively.

Regarding claims 55 and 56, the sleeves are fixedly or releasably attached to the corresponding cuff members (see entire document, especially col. 3, lines 35-44 of Masciarotte).

Regarding claim 57, one of the short edge portions of the sleeve is configured to be releasably attachable to the cuff member so as to define a closed sleeve having an axially extending aperture (see entirety of McCormick, Masciarotte, especially fig. 2B of McCormick and col. 3, lines 35-44 of Masciarotte).

Regarding claim 58, the rib support member has an elongate flexible body configured to inhibit an upper edge portion of the sleeve from rolling down (see entire document, especially fig. 2B of McCormick).

Regarding claim 59, the sleeve comprises at least one rib channel sized and configured to hold the rib member therein (see entire document, especially fig. 1 of McCormick).

Regarding claims 61 and 62, a kit of replacement sleeves are included which are configured to be individually selectably releasably attachable to the cuff members (see entire document, especially col. 5, lines 50-57 of McCormick). With further regard to claim 62, the sleeves are arranged in different predetermined sizes and are configured to be disposable single-use sleeves (see entire document, especially col.3, lines 37-38; col. 5, lines 50-57 of McCormick).

As to the language "ambulatory" in claim 63 and "stress test" in claim 64, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art since Marks, as modified teaches all of the

claimed structural elements and their recited relationships. The assembly of Marks, as modified, is certainly capable of being used on an ambulatory patient or during a stress test, as claimed.

Allowable Subject Matter

Claims 21, 24, and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

With regard to claim 21, the prior art of record fails to teach or fairly suggest an inflatable blood pressure assembly comprising a sleeve that is attached to the inflatable elongate cuff member, has at least one rib support member, and comprises a sensor chamber having a lower edge portion that is open, in combination with all of the other limitations of the claim.

With regard to claims 21 and 24 the prior art of record fails to teach or fairly suggest an inflatable blood pressure assembly comprising a sleeve that is attached to the inflatable elongate cuff member, has at least one rib support member, and comprises a cable channel in communication with the sensor chamber, the cable channel including an intermediate segment that is arcuate, a lower first segment that is substantially longitudinal, and an upper segment above the arcuate segment that includes lateral directional components, in combination with all of the other limitations of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Supervisory Patent Examiner
Art Unit 3735

for
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